CENTER FOR VETERINARY MEDICINE
PROGRAM POLICY AND PROCEDURES MANUAL GUIDE 1243.3060

OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

FINAL DOCUMENT ROUTING AND COPY DISTRIBUTION FOR NADAs, ANADAs, INADs, JINADs, MASTER FILES, AND SUITABILITY PETITIONS

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

I. PURPOSE

This Guide describes current procedures used for:

- final document routing and
- copy distribution for final action letters, Memoranda, and Freedom of Information Summaries.

II. PROCEDURES

The reviewer should prepare the various final documents as described in the CVM Policy and Procedures Guides (CVM P&P Guides) 3000 and 3100 series covering INAD/JINAD and NADA/ANADA review, including CVM P&P Guide 1240.3122, Routing of NADA Decision Package.

All final packages are forwarded with a STARS Routing and Transmittal Sheet. The STARS Routing and Transmittal Sheet is a final action worksheet, which is affixed to each final package for transmittal. The sheet accompanies the package in the signature process and STARS tracking system. The STARS Routing and Transmittal Sheet is posted on the CVM Network. When a final package is forwarded, the reviewer or Team Leader should ensure that document routing is indicated on the STARS sheet to obtain the proper signatures, and to route the package through HFV-103, Document Control Unit, where tracking and logging takes place.

Distribution copies of the letter:
The reviewer should add a *cc: block* at the end of letters and other final documents, and also mark each copy to indicate distribution. (Each destination is circled to show the appropriate unit as designated in the cc: block; and/or the name of recipient or other destination can be written in the upper-right-hand corner of the first page). The following is an example *cc: block*:

cc: HFV-199, NADA Orig.
HFV-*xxx*, Smith
JLJones, HFV-*xxx*, 12/1/01

The final document routing differs for the divisions within the Office of New Animal Drug Evaluation. The following sections describe the final document routing and copy distribution for submission types and documents commonly handled in each division.

III. FILE NO REPLY (FNR) FOR NADAs, ANADAs, INADs, JINADs, AND MFs

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-199

Distribution:
[no cc: copies for FNRs]

IV. FILE NO REPLY (FNR) WITH A MEMO FOR NADAs, ANADAs, INADs, JINADs, AND MFs

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-199

Distribution:
cc: HFV-199, NADA/ANADA/INAD/JINAD/MF Orig.
[filed by HFV-199 in the original NADA/ANADA/ INAD/JINAD, or MF open volume]

<Author's name, HFV-#, date>

Concur: *<Team Leader's Name>* [as per division SOPs]

V. ACKNOWLEDGMENT LETTER FOR NADAs, ANADAs, INADs, JINADs, AND MFs

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-199

Distribution:
cc: HFV-199, NADA/ANADA (INAD/JINAD, MF) Orig.
[salmon copy is filed by HFV-199 in the original NADA/ANADA/INAD/JINAD, or MF open volume].

<Author's name, HFV-#, date>

Concur: *<Team Leader's Name>* [as per division SOPs]

ACK

VI. GENERAL CORRESPONDENCE LETTER FOR NADAs, ANADAs, INADs, JINADs, AND MFs

Routing:
General Correspondence letters – same document routing and copies as Acknowledgment letters (above).

Distribution:
Same document routing and copies as Acknowledgment letters (above), except substitute "GEN" for "ACK."

VII. INAD/JINAD SLAUGHTER AUTHORIZATION - FOR AQUACULTURE AUTHORIZATIONS SEE SECTION VIII

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-102
HFV-100 [*Director, ONADE has Signature Authority*]
HFV-103
HFV-199

Distribution:
cc: HFV-199, INAD/JINAD Orig. [salmon]
HFV-*xxx*, Specialty Reviewer Copies
USDA/FSIS

<Author's name, HFV-#, date>

AUTH [or AMENDED AUTH]

[Enclosure: Notice of Claimed Investigational Exemption/Drug Shipment Notice. The Drug Shipment Notice is an enclosure with each Authorization Letter].

VIII. AQUACULTURE - EMERGENCY COMPASSIONATE INADs/JINADs

The Routing and Distribution for the Emergency Follow-Up Letter is shown below. The routing and clearance for the immediate handling of the request is given in the CVM P&P Guide 1243.4240, Aquaculture – Procedures for Emergency Compassionate INADs/JINADs.

Routing:
HFV-# for team
HFV-# for division
HFV-103
HFV-102
HFV-100 [*Director, ONADE*]
HFV-103
HFV-199

Distribution:
cc: HFV-199, INAD/JINAD Orig. [salmon]
HFV-*xxx*, Specialty Reviewer Copies
HFV-150, Aquaculture

<Author's name, HFV-#, date>

AUTH [or AMENDED AUTH]

NOTE: USDA/FSIS is not copied.

Enclosures: Notice of Claimed Investigational Exemption, Drug Shipment Notice, and other enclosures as described in Reviewers' Manual Guide 1243.4240.

IX. INCOMPLETE LETTER FOR NADAs/ANADAs (ORIGINALS, SUPPLEMENTS, AND ANNUAL REPORTS), INADs/JINADs (TECHNICAL SECTION) AND MASTER FILES

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-199

Distribution:
cc: HFV-199, NADA/ANADA/INAD/JINAD/MF [salmon copy in original NADA or MF volume]
HFR-*XXxxx* (District)-DO [Domestic Only]

<Author's name, HFV-#, date>

Concur: *<Team Leader's Name>* [as per division SOPs]

INC

X. UNACCEPTABLE CHANGES BEING EFFECTED (CBE) LETTER FOR NADAs/ANADAs SUPPLEMENTS

Routing:
HFV-# for team
HFV-# for division [The Division Director of HFV-140 signs the unacceptable CBE letter]
HFV-103
HFV-199
HFV-# for team

Distribution:
cc: HFV-199, NADA/ANADA Orig. [salmon]
HFV-*xxx*, Specialty Division Reviewer Copies
HFR-*XXxxx* (District)-DO (Domestic only)

<Author's name, HFV-#, date>

Concur: *<Team Leader's Name>*

XI. INAD-TECHNICAL SECTION COMPLETE LETTER AND MANUFACTURING SUPPLEMENTAL (NADA/ANADA) APPROVAL LETTER WITH OR WITHOUT REGULATION (CATEGORY I AND II)

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-199

Distribution:
cc: HFV-199, NADA/ANADA Orig. [salmon]
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

Concur: *<Team Leader's Name>* [as per division SOPs]

NOTE: For approval letters with regulation routing usually includes the Quality Assurance Team (HFV-102) before the document goes to HFV-103 with the exception of HFV-140. The Director of the Division of Manufacturing Technologies, HFV-140, has signature authority for approval of certain supplements described in 21 CFR 514.8 (a)(4)(iii) (iv) and (v) and 21 CFR 514.8 (d)(3), including those involving a change in the regulation (e.g., packaging size change for a soluble powder).

XII. SUPPLEMENTAL APPROVAL LETTER WITHOUT REGULATION (CATEGORY I AND II) - FOR MANUFACTURING SUPPLEMENTAL APPROVALS SEE SECTION XI

Routing:
HFV-# for team
HFV-# for division [as per division SOPs]

HFV-103
HFV-102
HFV-103
HFV-100 [*Director, ONADE has Signature Authority*]
HFV-103
HFV-102
HFV-103
HFV-199

Distribution:
cc: HFV-199, NADA/ANADA Orig. [salmon]
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

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NOTE: A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the cc: block). Guidance on FDA DOs is provided in P&P Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

XIII. ORIGINAL NADA AND SUPPLEMENTAL NADA CATEGORY II APPROVALS THAT INVOLVE NEW CLAIM, NEW SPECIES, OR RX/OTC CHANGE WITH REGULATION - FOR MANUFACTURING SUPPLEMENTAL APPROVALS SEE SECTION XI

Routing for the Approval Package:
HFV-# for team
HFV-# for division [as per division SOPs]
HFV-103
HFV-150 (*as appropriate*)
HFV-103

HFV-102
GCF-1 (*as appropriate*)
HFV-103
HFV-100
HFV-1 [*Director, CVM, has Signature Authority*]
HFV-102
HFV-103
HFV-199

Distribution copies for the Contents of the Approval Package:

A. Approval Letter:

cc: HFV-199, NADA/ANADA Orig. [salmon]
HFV-102, Reserve copy
HFV-102, Green Book
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

APP

NOTES:

Send only one copy of the ***draft*** Approval Letter initially with the Approval Package. After all necessary parties concur (and General Counsel concurs for certain approvals), the necessary corrections are made, and then the reviewer makes all the copies as outlined above.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the cc: block). Guidance on FDA DOs is provided in P&P Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

B. Memorandum Recommending Approval (MRA):

cc: HFV-199, NADA/ANADA Orig.
HFV-102, Green Book

<Author's name, HFV-#, date>

NOTES:
Send only one copy of the ***draft*** MRA initially with the Approval Package. After all necessary parties concur (and General Counsel concurs for certain approvals), the necessary corrections are made, and then the reviewer makes all the copies as outlined above.

No salmon copy is needed. Because the original MRA is retained in the jacket, there is no salmon copy.

C. FOI Summary:

cc: Courtesy copy for the sponsor (with no cc's listed on copy)
HFV-199, NADA/ANADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12, FOI Staff (with no cc's listed on copy)
HFV-102, Reserve Copy
HFV-102, Green Book
HFV-120 Labeling project
HFA-305, Dockets Management Branch (with no cc's listed on copy)
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

NOTES:
Send only one copy of the ***draft*** FOI Summary initially with the Approval Package.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the cc: block). Guidance on FDA DOs is provided in P&P Guide 1243.3300, Copies of Correspondence to FDA District Offices: www.fda.gov/cvm/index/policy_proced/ppindex.html

XIV. CATEGORY I SUPPLEMENTAL APPROVALS WITH REGULATION AND CATEGORY II SUPPLEMENTAL APPROVALS NOT COVERED BY SECTION XII - FOR MANUFACTURING SUPPLEMENTAL APPROVALS SEE SECTION XI

Routing for the Approval Package:
HFV-# for team
HFV-# for division
HFV-103
HFV-102
HFV-103
HFV-100 [*Director of ONADE has signature authority*]
HFV-102
HFV-103
HFV-199

Distribution Copies for the Contents of the Approval Package
A. Approval Letter:

cc: HFV-199, NADA/ANADA Orig. [salmon copy]
HFV-102, Green Book
HFV-102, Reserve Copy
HFV-*xxx*, Specialty Division Reviewer Copies
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

Enclosure FOI Summary

APP

NOTE: Send only one copy of the ***draft*** Approval Letter initially with Approval Package. After all necessary parties concur (and General Counsel concurs for certain approvals), the necessary corrections are made, and then reviewer makes all the copies as outlined above.

B. MRA:

cc: HFV-199, NADA/ANADA Orig.
HFV-102, Green Book

<Author's name, HFV-#, date>

NOTES:
Send only one copy of the ***draft*** MRA initially with the Approval Package. After all necessary parties concur (and General Counsel concurs for certain approvals), the necessary corrections are made, and then reviewer makes all the copies as outlined above.

No salmon copy is needed. Because the original MRA is retained in the jacket, there is no salmon copy.

C. FOI Summary:

cc: Courtesy copy for the sponsor (with no cc's listed on copy)
HFV-199, NADA Orig. [white copy]
HFV-2, Special Mailing List
HFV-12, FOI Staff (with no cc's listed on copy)
HFV-102, Reserve Copy
HFV-102, Green Book
HFV-120, Labeling Project (all feed drugs)
HFA-305, Dockets Management Branch (with no cc's listed on copy)
HFR-*XXxxx* (District)-DO [Domestic only]

<Author's name, HFV-#, date>

NOTES:
Reviewers, send forward only one copy of the FOI Summary initially with the Approval Package. After all necessary parties concur (and General Counsel concurs for certain approvals), the necessary corrections are made, and then reviewer makes all the copies as outlined above.

A copy should be provided to the FDA DO for a sponsor's headquarters and for any FDA DOs identified in the HFV-140 Technical Section Complete letter or Manufacturing Chemistry Review Memoranda (as indicated in the cc: block). Guidance on FDA DOs is provided in P&P Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

XV. SPECIALTY REVIEW FOR NADAs/ANADAs/INADs/JINADs (ORIGINAL)

Routing the Request and the return:
HFV-# for team
HFV-103
Specialty Division HFV-#
HFV-103
HFV-# for the team that made the request (return)

Distribution:
cc: HFV-199, NADA/ANAD/INAD/JINAD Orig.

<Author's name, HFV-#, date>

XVI. SUITABILITY PETITION (SP) DECISION

Suitability Petitions are processed by the Quality Assurance Team, HFV-102. The process is described in CVM P&P Manual, Guide 1240.2030, Citizen Petitions and Suitability Petitions: Policy and Procedures.

Purpose: For Generic Drugs, when there is some question about the suitability of a particular product to qualify for abbreviated NADA status, the sponsor may submit a Suitability Petition. If approved, the product then qualifies, and the sponsor includes a copy of the SP approval letter with the actual ANADA submission.

Initial Processing: The SP is formally filed through Dockets Management Branch, HFA-305 and is then forwarded to the Quality Assurance Team, HFV-102. The letter granting or denying the SP is prepared with concurrence of General Counsel (if appropriate), and is routed through GADQC Staff Chief for final sign-off by the ONADE Director.

Tracking: The SP is not entered into STARS, but a logbook is kept in HFV-102 of all SPs submitted and responses. The Dockets Management Branch, HFA-305, also maintains a formal record.

Routing:
HFV-102
GCF-1 (as appropriate)
HFV-102
HFV-100 [*Director, ONADE has Signature Authority*]
HFA-305

Distribution:
cc: HFA-305, Dockets Management Branch [Dockets copy lists no other cc: copies]
HFV-102, Green Book
HFV-101 Generics File Copy
GCF-1, GC copy

<Author's name, HFV-#, date>

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

SP GRANTED or SP DENIED

NOTE: There is usually no ANADA established at this time for filing. This copy is for HFA-305. It is a copy of the dated and signed letterhead letter.

XVII. DOCUMENT SUMMARY, SCIENTIFIC REVIEW, OR INTERNAL MEMORANDUM

Distribution copies for Document Summary:

cc: HFV-199, NADA/INAD Orig. [white or yellow]

<Author's name, HFV-#, date>

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

Distribution copies for an internal memorandum, including a scientific review memorandum:

cc: HFV-199, NADA Orig. [yellow]
HFV-*xxx* (If an internal Specialty Review, copy to the Specialty Team or Division File, as appropriate)
HFV-*xxx*, Primary Review Team or Division File [as per division SOPs]
HFV-*xxx* (Other Center copies: For example, persons involved in the decision or action; attendees at the conference, etc.)

<Author's name, HFV-#, date>

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

XVIII. REFERENCES

Section 512 of the Federal Food, Drug, and Cosmetic Act

DHHS/PHS/FDA. 1989. Food and Drug Administration Correspondence Manual

Code of Federal Regulations, 21 CFR 511.1 (b), New Animal Drugs for Clinical Investigation in Animals; 21 CFR part 5, Delegations of Authority and Organization

CVM Policy and Procedures Manual, Guide 1240.3000 series, New Animal Drugs for Investigational Use

CVM Policy and Procedures Manual, Guide 1240.3100 series, Processing New Animal Drug Applications

CVM Policy and Procedures Manual, Guide 1240.3122, Routing of NADA Decision Package

CVM Policy and Procedures Manual, Guide 1240.2030, Citizens Petitions or Suitability Petitions: Policy and Procedures

CVM Policy and Procedures Manual, Guide 1243.4240, Aquaculture – Procedures for Emergency Compassionate INADs/JINADs

CVM Policy and Procedures Manual, Guide 1243.4150, Food-Use Authorization Letters; Original and Amended